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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 35

Application Number: 08/894,788
Filing Date: August 27, 1997
Appellant(s): GIACOMONI, PAOLO

Michelle E. O'Brien
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 7-30-03.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the

pending appeal is contained in the brief. Therefore, it is presumed that there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existence of any related appeals and interferences.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 31-38, 40-54 and 56-66 stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,716,625	Hahn et al.	2-1998
5,449,688	Wahl et al.	9-1995
5,358,969	Williamson et al.	10-1994

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 U.S.C. § 103

Claims 31-38, 40-54 and 56-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over

1) Hahn et al in view of Williamson et al OR

2) Hahn et al in view of Wahl et al OR

3) Hahn et al in view of Williamson et al and Wahl et al.

Hahn teaches a number of substances, which when applied topically can cause skin irritation. The substances include vehicles in which active ingredients are formulated (carriers), solvents, detergents, fragrances, propellants, salicylic acid derivatives, retinoids etc., and cause irritation which ranges from mild irritation to severe dermatitis conditions. Further, Hahn teaches that people with sensitive skin has an inherent predisposition to skin irritants, for example, people with skin conditions such as psoriasis, contact dermatitis etc., (see col. 3, lines 27-43). Hahn teaches strontium cation as an anti-irritant (see entire document, particularly, cols. 1-4, 10 and 11), suggesting in general the use of anti-irritant together with an irritant, in the same composition. However, Hahn fails to teach the claimed nitric oxide (NO) synthase inhibitor as anti-irritant.

Williamson teaches NO synthase inhibitors, such as like methyl-, dimethyl or amino substituted guanidines, for the treatment of chronic and acute inflammatory conditions (column 2, lines 44-54; col. 3, lines 13-18). Williamson also recognizes N-monomethyl-L-arginine, as a

NO synthase inhibitor (col. 1, lines 60-65). The acute and chronic inflammatory conditions taught by Williamson include dermatitis, drug reactions, sunburn, insect bites, burns (thermal, chemical and electrical) (column 3, lines 38-45). Williamson et al also teaches pharmaceutically acceptable diluents and carriers (see col. 11, lines 35-39), which according to Hahn et al are capable of producing skin irritation.

A skilled artisan would be motivated to incorporate NO synthase inhibitors of Williamson et al as anti-irritants in the composition of Hahn et al containing irritant chemical and expect to counteract the irritant because Williamson et al teach NO synthase inhibitors are capable of inhibiting chemical induced chronic and acute dermatitis and Hahn teaches that chronic and acute dermatitis results due to the irritation caused by chemicals. Therefore, it would have been obvious for a skilled artisan to substitute the strontium cation of Hahn et al with NO synthase inhibitors of Williamson et al, with an expectation to inhibit the irritation by caused by the substances of Hahn et al. Williamson does not teach topical application of nitric oxide synthase inhibitor. However, applying nitric oxide synthase inhibitors of Williamson et al as a topical formulation would have been obvious from the teachings of Hahn et al, or alternatively, it is within the scope of a skilled artisan at the time of the instant invention to use topical formulations of nitric oxide synthase inhibitors as first line of choice, with an expectation to produce a local effect.

Wahl et al teaches treatment of chronic inflammatory conditions such as psoriasis (paragraph bridging cols. 3 and 4), by administering the specific nitric oxide synthase inhibitors of the instant claims (see col. 3, lines 39-68). Wahl teaches several routes of administration,

including topical application (col. 6, lines 53-65). Thus, Wahl et al teaches the same skin conditions, which have a predisposition to be irritated upon exposure to common cosmetic and pharmaceutical products of Hahn et al, and suggests topical application of nitric oxide synthase inhibitors. Therefore, it would have been obvious for a skilled artisan at the time of the instant invention to use the nitric oxide synthase inhibitors of Wahl (and Williamson et al) in the topical composition of Hahn et al, with an expectation to inhibit the skin irritation caused by the various chemicals (Hahn et al).

(11) Response to Argument

Applicants argue that Hahn is not generic with respect to the teaching of anti-irritants, as Hahn does not teach substitution of strontium cation with any other anti-irritant. Applicants also argue that examiner has not pointed to any teaching of Hahn that would have motivated a skilled artisan to replace the strontium cation of Hahn with a NO synthase inhibitor of Williamson or Wahl. Furthermore, applicants argue that Hahn discloses one method of treatment using one compound for one condition, while both Williamson and Wahl discloses a different method of treatment using different compound for a different condition.

The above arguments have been considered but they are not persuasive because, the combination of strontium cation and irritants (of Hahn et al) suggests a general theory for having an irritant and anti-irritant in the same composition. More specifically, Hahn states that it is highly desirable to identify compounds with anti-irritant activity, that reduces irritation caused by exposure to irritating chemicals, environmental conditions such as sun, wind etc., or due to intrinsic irritation associated with skin conditions such as psoriasis (col. 4, lines 56-63). The

motivation to replace the strontium of Hahn et al with the nitric oxide synthase inhibitors of Williamson et al comes from the fact that both the references teach the treatment of same skin conditions (dermatitis, chemical and environmental irritation etc.). Williamson et al teaches nitric oxide synthase inhibitors as a treatment for dermatitis, sunburn etc., while Hahn teaches strontium chloride for the same. Therefore, it would have been obvious for a skilled artisan that NO synthase inhibitors (Williamson) are also effective anti-irritants for the treatment of dermatitis (Hahn and Williamson), caused due to chemical irritants.

Applicants argue that Hahn teaches topical application of strontium (II) chloride for counteracting the superficial skin irritation caused by topical application of cosmetic or pharmaceutical product, which is in contrast to the teachings of Williamson or Wahl because the latter references teach systemic administration for preventing inflammatory diseases caused by intracellular nitric oxide production. Applicants argue that in particular, the compounds of Wahl inhibit or limit the production of nitric oxide production by leukocytes as a means of preventing and treating chronic and acute inflammatory conditions which are caused by excess nitric oxide attacking the healthy cells, which is not the same as topical application of anti-irritants (taught by Hahn) because the solution of Williamson or Wahl is to the problem caused by the formation pf nitric oxide within the cells. Applicants' arguments are not persuasive because Wahl teaches inhibiting the nitric oxide at the site of inflammation. Accordingly, the site of inflammation in a chronic or acute inflammatory condition such as those described by Wahl (for example, psoriasis) is none other than topical because psoriasis is a skin condition. Further, Wahl clearly states that the compounds (nitric oxide inhibitors) can be applied topically, as transdermal patches, intravenously etc (col. 6, lines 53-55).

Applicants argue that unlike Wahl and Williamson, Hahn fails to teach systemically decreasing or preventing nitric oxide formation, and Hahn only teaches counteracting superficial skin irritation caused by topically applied irritants. This argument is not persuasive because, all the references are directed to skin inflammatory conditions (dermatitis, psoriasis) caused by chemical or physical agents, and Williamson and Wahl suggest that the inflammation in dermatitis or psoriasis, respectively, involves the increased production of nitric oxide. Thus, a skilled artisan would expect an increased nitric oxide production in the dermatitis conditions taught by Hahn (caused by irritants). Accordingly, it would have been obvious for a skilled artisan to incorporate NO synthase inhibitors in the composition of Hahn, with an expectation to inhibit the nitric oxide production and thus provide an effective treatment for dermatitis. Further, Wahl suggests topical application of NO synthase inhibitors. Accordingly, a skilled artisan would have expected NO synthase inhibitors of Williamson and Wahl to be effective as cutaneous anti-irritants, in the composition of Hahn.

Applicants argue that without the present disclosure a skilled artisan would not have any reason to use strontium cation and NO synthase inhibitors interchangeably because, the chemistry of these anti-irritants is completely different. However, as explained above, both Hahn and Williamson teach the treatment of skin conditions such as dermatitis caused by skin irritants. Therefore, a skilled artisan would expect to provide an effective treatment for dermatitis either by administering strontium (of Hahn) or NO synthase inhibitors (of Williamson or Wahl).

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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April 29, 2004

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